

REMARKS

This Amendment is submitted in response to an Office Action mailed on April 11, 2003, and also in connection with a Request for Continued Examination (RCE) filed concurrently herewith. By this amendment, claims 1, 4-11, and 14-21 have been amended, claims 22 and 23 have been cancelled, and claims 24-32 have been added.

Attached for the Examiner's convenience is a blackline version of the claims to indicate the amendments made thereto by this amendment.

In the Office Action, the Examiner made a final rejection of claims 1, 5-11 and 14-23 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,201,708 to Martin. Applicants' respectfully traverse that rejection.

Martin discloses a self-locking safety syringe having a pair of "locking tabs 52 and 54, which are designed to be compressed by finger of a user." Column 3, lines 22-25. The locking tabs permit repeated movement of the needle guard 12 between an extended position (in which the needle is covered), and a retracted position (in which the needle is exposed).

Applicants' invention, in contrast and as recited by the amended claims, is directed to a safety shield system for a needle cannula (see, e.g., claim 1) having a resilient finger with a free end portion that permits one-time movement of a shield from a first position (in which the needle is covered) to a second position (in which said needle is exposed), and from the second position back to the first position. Such a device is neither disclosed nor suggested by Martin, whether considered alone or in any proposed hypothetical combination of prior art and/or the knowledge of a person of ordinary skill in the art. Thus, applicants respectfully submit that the present invention, as recited by the amended and newly added claims, is patentable over the prior art of record.

In view of the foregoing remarks, applicants respectfully submit that this amendment is fully responsive to the Office Action. Applicants thus respectfully request early and favorable reconsideration of the present application.

Application No.: 10/072,691
Amendment Dated July 11, 2003
Reply to Office Action Of April 11, 2003

Applicants hereby authorize the Commissioner to charge any fees due in connection with the present application, including fees for the Petition for Extension of Time, if necessary, to Deposit Account Number 02-1666.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicants.

Respectfully submitted,

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By:



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1. A safety shield system for a needle cannula ~~having a lumen therethrough for transfer of fluid from a body having a generally tubular end portion~~, said safety shield system comprising :

~~a generally tubular clip member having a plurality of spaced laterally projecting resilient hook-shaped fingers each having an outwardly inclined~~ finger having a free end portion,

~~a generally tubular reciprocable shield including having a first portion surrounding said clip member, and a second portion normally surrounding said~~ having an opening through which the needle cannula and a plurality of spaced axially extending inwardly opening channel-shaped tracks on inside surface of said may freely pass, said shield receiving said laterally projecting resilient hook-shaped fingers of said clip member and guiding said shield axially from being freely movable between a first position wherein, in which said shield second portion surrounds said the needle cannula, to and a second position wherein said, in which the needle cannula is exposed, said shield having a track defined on an inside surface thereof, said track being sized and shaped to receive said resilient finger, said resilient finger moving in said track as said shield is moved between said first position and said second position, said track having an opening defined through a sidewall of said shield; and

~~a spring resiliently biasing said shield axially to normally extend said shield second first position;~~

said free end portion of said finger permitting one-time movement of said shield from said first position to said second position, and from said second position to said first position, said finger being biased to maintain contact between said finger and said sidewall of said shield;

wherein said free end portion of said resilient finger passes freely over said opening defined through said sidewall of said shield as said shield is first moved from said first position to said second position, and wherein said free end portion to surround said needle

~~cannula, wherein at least one of said channel-shaped tracks includes an opening through a sidewall of said shield which receives said end portion one of said fingers therethrough resilient finger passes through said opening when said shield is first retracted to moved from said second position and then extended to said first position by, said spring and free end portion interfering with said sidewall to prevent subsequent movement of said shield out of said first position thereby locking said shield in said first position.~~

4. The safety shield system defined in Claim claim 1, wherein said ~~one of said channel-shaped tracks track~~ includes an inwardly projecting resilient finger portion adjacent said opening resiliently biasing said ~~outwardly inclined portion of said one of said resilient hook-shaped fingers inwardly and releasably retaining said shield in said first position prior to retraction of said shield to said free end portion of said second position and said resilient hook-shaped finger in said track inwardly and~~ initially guiding said ~~one of said resilient hook-shaped fingers finger~~ over said opening when said shield is retracted first moved from said first position to said second position.

5. The safety shield system defined in Claim ~~1~~, wherein ~~said safety shield system includes claim 1, further comprising~~ a removable cup-shaped cap initially received over said shield.

6. The safety shield system defined in Claim claim 5, wherein said ~~needle cannula includes a generally cup-shaped hub and said needle cannula extends through said hub to define a first portion extending into said body portion to puncture a closure in a container opening received in said body, and a second end portion extending into said shield, said cup-shaped cap is configured to receive and retain said safety shield system and said needle cannula and hub assembly upon removal of said assembly from said body and reversal of said assembly to receive said first end portion of said needle cannula in said cap shield after use, thereby providing for safe disposal of said safety shield system and needle cannula.~~

7. The safety shield system as defined in Claim claim 6, wherein said cup-shaped cap includes internal radially projecting ribs which receive and retain said assembly first portion of said shield preventing movement of said shield when said cap is located on said shield.

8. The safety shield system defined in ~~Claim~~ claim 1, wherein said ~~plurality of fingers each include clip member~~ has a tubular body portion and wherein said finger includes a U-shaped portion integrally connected at ~~one end to a said~~ tubular body portion of said clip member.

9. The safety shield system defined in ~~Claim~~ claim 8, wherein said spring is a spiral spring having ~~one a first~~ end received in said U-shaped ~~portions~~ portion of said ~~fingers~~ finger, and ~~an a opposed second~~ end biased against said shield.

10. The safety shield system defined in ~~Claim~~ claim 9, wherein said shield is generally cup-shaped having an open end received around said clip member and a generally closed end having a central opening therethrough receiving ~~said the~~ needle cannula, and ~~said spiral spring having a second end portion biased against said generally closed end of said shield.~~

11. A ~~pen needle and~~ safety shield system, ~~said for use with a pen injector~~ having a generally tubular body portion for receiving a container of fluid having an open end and a closure in ~~said the~~ open end, a needle cannula assembly including a hub and needle cannula extending through ~~said the~~ hub and having a first end extending into ~~said the~~ pen-type injector body, and a second end extending away from ~~said the~~ pen-type injector body for injection and transfer of fluid from ~~said the body container~~ to a user-patient, said safety shield system including comprising:

~~a generally tubular clip member having a plurality of circumferentially spaced an end portion comprised of a resilient hook-shaped fingers each finger~~ having an outwardly inclined end portion, ~~a generally tubular reciprocable;~~

~~a shield including a having a first portion surrounding said clip member, a and a second portion normally surrounding said second end of said having an opening through which the needle cannula and a plurality of spaced axially extending inwardly opening channel-shaped tracks on an inside surface of said shield receiving said laterally projecting resilient fingers of said clip member and guiding said may freely pass, said shield axially from being freely movable between a first position wherein, in which said shield second portion surrounds said the needle cannula second end to, and a second position wherein said second end of said, in which the~~

needle cannula is exposed, said shield having a channel-shaped track defined on an inside surface thereof, said channel-shaped track being sized and shaped to receive said resilient hook-shaped finger, said resilient hook-shaped finger moving in said channel-shaped track as said shield is moved between said first position and said second position, said channel-shaped track having an opening defined through a sidewall of said shield; and

and a spring resiliently biasing said shield axially to normally extend said shield second portion to surround said needle cannula second end, wherein at least one of said channel-shaped tracks includes an opening through a side wall of said shield which receives first position;

said free end portion of said hook-shaped finger permitting one-time movement of said shield from said first position to said second position, and from said second position to said first position, said hook-shaped finger being biased to maintain contact between said outwardly inclined portion of one of said resilient hook-shaped fingers end portion and said sidewall of said shield;

wherein said outwardly inclined end portion of said hook-shaped finger passes freely over said opening defined through said sidewall of said shield as said shield is first moved from said first position to said second position, and wherein said outwardly inclined end portion of said hook-shaped finger passes through said opening when said shield is first retracted to moved from said second position and then extended to said first position by, said spring and outwardly inclined end portion interfering with said sidewall to prevent subsequent movement of said shield out of said first position thereby locking said shield in said first position to limit access to said second end of said needle cannula.

14. The ~~pen needle and safety shield system defined in Claim claim 11, wherein said one of said channel-shaped tracks in said shield track~~ includes a resilient ~~an~~ inwardly projecting resilient finger portion adjacent said opening resiliently biasing said ~~one of said fingers~~ outwardly inclined end portion of said hook-shaped finger inwardly and releasably retaining said shield in said first position prior to retraction of said shield to said second position and said resilient finger portion in said track initially guiding said one of said fingers hook-shaped finger

over said opening when said shield is first extended to said first position moved from said first position to said second position.

15. The ~~pen needle and safety shield system defined in Claim 1, wherein said safety shield system includes claim 11, further comprising~~ a removable cup-shaped cap having an open end initially received over said shield.

16. The ~~pen needle and safety shield system as defined in Claim claim 15, wherein said cup-shaped cap is configured to receive said safety shield system and needle cannula assembly upon removal of said safety shield system and needle cannula assembly from said body and reversal of said needle cannula assembly and safety shield system to receive retain~~ said first end portion of said needle cannula in said cap shield after use, thereby providing for safe disposal of said needle cannula assembly.

17. The ~~pen needle and safety shield system defined in Claim claim 11, wherein said plurality of fingers each clip member has a tubular body portion and wherein said hook-shaped finger includes a U-shaped portion integrally connected at one end to a said tubular body portion of said clip member and a radially projecting hook-shaped end portion received in said channel-shaped tracks.~~

18. The ~~pen needle and safety shield system defined in Claim claim 17, wherein said spring is a spiral spring having one a first end received in said U-shaped portions portion of said fingers hook-shaped finger, and an a opposed second end biased against said shield.~~

19. The ~~pen needle and safety shield system defined in Claim claim 18, wherein said shield is generally cup-shaped having an open end received around said clip member and a generally closed end having a central opening therethrough receiving said needle cannula and said spiral spring having a second end portion biased against said generally closed end of said shield.~~

20. The ~~pen needle and safety shield system defined in Claim claim 11, wherein said clip member includes a generally tubular body portion including a plurality of radially extending ribs and said shield includes a plurality of axially extending grooves which receives said ribs,~~

preventing rotation of said shield relative to said clip member and guiding said shield axially between said first and second positions.

21. A pen needle injector and safety shield assembly, comprising:

a pen needle injector having a generally tubular body portion including an open end;₂

a needle hub member having a generally tubular body portion received over said pen needle injector open end;₂

a needle cannula secured by said needle hub having a first end extending into said tubular body portion of said pen needle injector and an opposed second end, ~~a clip member having a generally tubular body portion mounted on said tubular body portion of said hub member having a plurality of radially extending ribs, a generally cup-shaped retractable shield including a tubular body portion having an open end, a generally closed end portion having a central opening therethrough receiving said second end portion of said needle cannula therethrough, and a plurality of radial grooves extending through a side wall of said tubular body portion from adjacent said generally closed end portion to adjacent said open end of said tubular body portion receiving said radially extending ribs of said clip member through said side wall, and a cup-shaped cap having a plurality of inwardly projecting ribs received in said grooves in said shield to adjacent said ribs on said clip member preventing retraction of said shield when said cap is located on said shield.~~₂

a clip member having a resilient finger having a free end portion;

a shield having a first portion surrounding said clip member and a second portion having an opening through which the needle cannula may freely pass, said shield being freely movable between a first position, in which said second portion surrounds said needle cannula, and a second position, in which said needle cannula is exposed, said shield having a track defined on an inside surface thereof, said track being sized and shaped to receive said resilient finger,

said resilient finger moving in said track as said shield is moved between said first position and said second position, said track having an opening defined through a sidewall of said shield; and

a spring biasing said shield axially to said first position;

said free end portion of said finger permitting one-time movement of said shield from said first position to said second position, and from said second position to said first position, said finger being biased to maintain contact between said finger and said sidewall of said shield;

wherein said free end portion of said resilient finger passes freely over said opening defined through said sidewall of said shield as said shield is first moved from said first position to said second position, and wherein said free end portion of said resilient finger passes through said opening when said shield is moved from said second position to said first position, said free end portion interfering with said sidewall to prevent subsequent movement of said shield out of said first position thereby locking said shield in said first position.

22. Cancelled.

23. Cancelled

24. The pen injector and safety shield system defined in claim 21, wherein said track includes an inwardly projecting resilient finger portion adjacent said opening resiliently biasing said free end portion of said resilient finger inwardly and initially guiding said resilient finger over said opening when said shield is first moved from said first position to said second position.

25. The pen injector and safety shield system defined in claim 21, further comprising a removable cup-shaped cap initially received over said shield.

26. The pen injector and safety shield system defined in claim 25, wherein said cup-shaped cap is configured to receive and retain said first portion of said shield after use, thereby providing for safe disposal of said safety shield system and needle cannula.

27. The pen injector and safety shield system as defined in claim 26, wherein said cup-shaped cap includes internal radially projecting ribs which receive and retain said first portion of said shield preventing movement of said shield when said cap is located on said shield.

28. The pen injector and safety shield system defined in claim 21, wherein said clip member has a tubular body portion and wherein said finger includes a U-shaped portion integrally connected to said tubular body portion of said clip member.

29. The pen injector and safety shield system defined in claim 28, wherein said spring is a spiral spring having a first end received in said U-shaped portion of said finger, and a second end biased against said shield.

30. The pen injector and safety shield system defined in claim 9, wherein said shield is generally cup-shaped having an open end received around said clip member and a generally closed end having a central opening therethrough receiving the needle cannula.

31. The safety shield system defined in claim 1, wherein said finger is hook-shaped and includes an outwardly inclined end portion that interferes with said sidewall to prevent subsequent movement of said shield out of said first position thereby locking said shield in said first position.

32. The pen needle and safety shield system as defined in claim 15, wherein said cup-shaped cap includes internal radially projecting ribs which receive and retain said first portion of said shield preventing movement of said shield when said cap is located on said shield.